

REMARKS

No amendments have been made. Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 43-46, 48, and 52-58 are presented for the Examiner's review and consideration. Applicants believe the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Finality of Office Action

Upon receipt of the current Office Action, Applicants noted that although both public PAIR and the Office Action Summary indicate that the Office Action is non-final, item 9 (the conclusion of the Office Action) states that the action is a final action. Applicants request clarification of the status of the current Office Action. In this regard, Applicants respectfully submit that finality would not be proper in light of the Request for Continued Examination filed July 6, 2009, which included claim amendments.

Rejections under 35 U.S.C. §103(a)

Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 42-46, and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 3,513,848 to Winston et al. ("Winston") in view of U.S. Patent No. 5,908,429 to Yoon ("Yoon"). Claims 52-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winston in view of Yoon and further in view of U.S. Patent No. 6,348,056 B1 to Bates et al. ("Bates").

For reasons set forth below, Applicants respectfully submit that both of these rejections should be withdrawn. It is noted that the cited references have been discussed in detail in previous Responses, and these discussions are incorporated herein by reference in the interest of brevity.

The invention as claimed provides a surgical device for securing tissue, the device including an elongated insulation sleeve that is controllably positionable over a second member,

a tubular member, and/or a force-transmitting member. The positionability of the elongated insulation sleeve limits application of energy to a retainer and/or the gapped portion of the device. Likewise, when the retainer is used with a suture, the suture is shielded from the energy. Additionally, when the device is in use the surrounding tissue is protected from potentially-damaging contact with the energy. In one embodiment (claim 35), a safety switch prevents energy from being applied until the elongated insulation sleeve is in a certain position.

Applicants respectfully submit that the combination of the teachings of Winston and Yoon or of Winston, Yoon, and Bates does not obviate the invention as claimed. The obviousness rejection is based on the premise that Winston discloses the device as claimed with the exception of a specific compressive force and an insulating sleeve and that Yoon supplements these teachings by disclosing an instrument designed to transmit various forms of energy controllably positioned into an insulated sleeve. Therefore, it is asserted, that it would have been obvious to one of ordinary skill in the art to produce the claimed device by providing Winston with the sleeve of Yoon.

Applicants respectfully disagree. The combination of references neither provides nor suggests a device as currently claimed. As explained in the last Response, each of the independent claims recites that the insulation sleeve is movable. With Yoon, the instrument slides within a stationary sleeve. In the claimed invention, the insulation sleeve is not stationary, but rather slides over the second/tubular member. As described by Yoon, a tissue-grasping instrument **16** is longitudinally movable with regard to barrel **12** such that the distal end of the grasping instrument can be retracted or drawn into the barrel, *i.e.* the tissue-grasping instrument **16** slides within barrel **12** and barrel **12** does not slide over the tissue-grasping instrument **16**. Thus, the barrel **12** is stationary with respect to other elements of the device. In fact, Yoon specifically discloses that the grasping instrument **16** is retractable for safety and protection of the instrument itself. *See* column 8, lines 34-59; and Figures 1, 2, and 5. Thus, with Yoon, it is the instrument that moves and not the barrel.

Applicants also submit that it would not be possible to combine Winston with Yoon to obtain the invention as claimed. Yoon discloses sleeves **28A**, **28B**, and **28C** disposed within and fixedly secured to barrel **12**. *See* column 5, line 65-column 6, line 18. As a result, the

movement/positionability of the sleeve of the currently-claimed device is impossible to achieve using either the barrel or the sleeves of Yoon's device with Winston's device.

Furthermore, the utilization of energy by Winston's device is totally different than the utilization of energy by Yoon's device. In particular, energy is not applied to the same elements to achieve the same results.

In Winston, ultrasonic energy is applied to secure overlapped free end segments of suture material. *See* column 3, line 69-column 4, line 12. In other words, energy is applied directly to the suture(s) by Winston. Winston does not describe any element of the device useful to limit/control application of energy to the suture and/or to protect the surrounding tissue from potentially-damaging contact with the energy. In Yoon, energy is applied directly to the tissue for ligation. *See* column 2, lines 1-10; column 4, lines 47-48; column 8, lines 34-35; column 18; lines 20-30; and Figure 24. Yoon does not describe any element of the device useful to apply and/or limit application of energy to the ligature material/suture or to limit/control the amount of energy applied to the tissue.

It is clear from the above discussions that the combination of the teachings of Winston and Yoon lacks all of the elements of the device as currently claimed; *i.e.* the combination does not describe an elongated insulation sleeve that is controllably positionable to provide precise control of the energy utilized for bonding of the sutures or retainers while simultaneously protecting the surrounding tissues from potentially-damaging contact with the energy. Therefore, merely surrounding the device of Winston with the sleeve of Yoon would not result in the device of the claimed invention, but rather with a non-functional device in which the energy source to the overlapped ends of a suture is blocked by an immobile sleeve.

Even if one incorrectly determined that the combination of Winston and Yoon teaches all of the elements of the claimed invention, the fact that one reference discloses an element(s) of an invention and a second reference discloses another element(s) does not, in and of itself, render the claimed invention an obvious combination of the two references. In other words, there must be some motivation, other than impermissible hindsight to combine the references as suggested in the Office Action to obtain the invention as claimed.

Applicants respectfully submit that, if anything, the references teach that a protective sleeve as set forth in Yoon would not be necessary for Winston's device. Since Winston teaches that his device is useable at "cool temperatures" and that it can engage biological tissue without causing damage, why would one be motivated to cover the device with a sleeve positionable to limit/control application of energy to sutures and/or tissues? Adding a sleeve to Winston would potentially limit the strength of the bond of the suture. If Winston is safe for tissue without a sleeve as Winston teaches, why would one of ordinary skill risk a weak suture-to-suture bond by using a sleeve?

Neither the cited patents (Winston and Yoon) nor any other cited prior art teach or suggest a surgical device for securing tissue; the device including an elongated insulation sleeve that is controllably positionable over the second/tubular member to provide precise control of the energy utilized for bonding of the sutures and/or retainers while simultaneously protecting the sutures, retainers, and/or surrounding tissues from potentially-damaging contact with the energy. Additionally, considering that devices for securing tissue are absent from the disclosure of Bates, the addition of Bates as a secondary reference does nothing to remedy the deficiencies of the combination of Winston and Yoon. Thus, even if one of ordinary skill in the art were to combine the teachings of Winston and Yoon and/or of Winston, Yoon, and Bates, the surgical device as claimed would not be the result.

Accordingly, Applicants submit that independent claims 1, 24, 25, 35, 43, 44, and 48 are patentable over Winston in view of Yoon and Winston in view of Yoon and further in view of Bates. As claims 2-5, 7, 8, 10, 14-20, 22, 23, and 52 depend from claim 1; claim 53 depends from claim 24; claim 54 depends from claim 25; claims 36-39, 45, 46, and 55 depend from claim 35; claim 56 depends from claim 43; claim 57 depends from claim 44; and claim 58 depends from claim 48, these dependent claims necessarily include all the elements of their respective base claim. Thus, Applicants respectfully submit that these dependent claims are allowable over Winston in view of Yoon and Winston in view of Yoon and further in view of Bates at least for the same reasons.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 43-46, 48, and 52-58 under 35 U.S.C. §103(a).

Conclusion

Accordingly, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a one month extension of time pursuant to Section 1.17(a)(2) in the amount of \$65 is believed to be due and is being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-024).

Respectfully submitted,

/Paul D. Bianco/

Paul D. Bianco, Reg. # 43,500
Customer Number: 33771
FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@fggbb.com